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UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: John S. Patton et al.

Atty. Docket No.: 0005.16

Examiner: Unassigned

Application No.: 10/613,078

Filed: 07/01/2003

Title: METHODS AND COMPOSITIONS
FOR THE PULMONARY DELIVERY
INSULIN

Atty. Docket No.: 0005.16

Examiner: Unassigned

Group Art Unit: Unassigned

ORDON OF THE PULMONARY DELIVERY

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on OSNOVOY

signed: Munna Cotter

<u>UNDER 37 CFR §1.56, §1.97 and §1.98</u>

Assistant Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

The references on the attached Form PTO/SB/08A and B identified by an asterisk (*) were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date.

Accordingly, in compliance with 37 CFR §§1.98 (d), copies of these references have not been provided.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed: \boxtimes within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last); more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by: the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00) Please charge the amount of \$_____ to Deposit Account 500348 If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348. Respectfully submitted, **NEKTAR THERAPEUTICS** Dated: 14/1/2004 By: Reg. No. 45,302 San Carlos, CA 94070 (650) 631-3100

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Form PTO/SB/08A Modified)	Atty Docket No.: 0005.16	Application No.: 10/613,078
Information Disclosure Statement By Applicant	Applicant: John S. 1	Patton et al.
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner						Sub-	Filing
Initial		Patent No.	Date	Patentee	Class	Class	Date
	*	2,598,525	05/1952	Fox			
	*	3,202,731	08/1965	Grevenstuk et al.			
	*	3,300,474	01/1967	Flodin et al.			
	*	3,314,803	04/1967	Tarrytown et al.			
	*	3,362,405	01/1968	Hazel			
	*	3,425,600	02/1969	Ablanalp			
	*	3,540,927	11/1970	Niimi et al.			
	*	3,554,768	01/1971	Feldman			
	*	3,620,776	11/1971	Mishkin et al.			
	*	3,666,496	05/1972	Honey et al.			
	*	3,674,901	07/1972	Shepherd et al.			
	*	3,764,716	10/1973	Rainwater et al.			
	*	3,921,637	11/1975	Bennie et al.			
	*	3,937,668	02/1976	Zolle			
	*	3,964,483	06/1976	Mathes			
	*	3,971,852	07/1976	Brenner et al.			
	*	3,991,304	11/1976	Hillsman			
	*	3,991,761	11/1976	Cocozza			
	*	3,994,421	11/1976	Hansen			
	*	4,036,223	07/1977	Obert			
	*	4,069,819	01/1978	Valentini et al.			
	*	4,098,273	401/1978	Glenn			
	*	4,109,019	08/1978	Moore			
	*	4,153,689	05/1979	Hiral et al.			
	*	4,206,200	06/1980	Guthohrlein et al.			
	*	4,211,769	07/1980	Okada et al.			
	*	4,249,526	02/1981	Dean et al.			
	*	4,253,468	03/1981	Lehmbeck			
	*	4,294,624	10/1981	Veltman			
	*	4,294,829	10/1981	Suzuki et al.			

Examiner:	Date Considered:

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:	
	0005.16	10/613,078	
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(Use Several Sheets if Necessary)	07/01/2003	1616	

Initial	Examiner						Sub-	Filing
* 4,423,079 12/1983 Kline * 4,446,862 05/1984 Baum et al. * 4,448,577 11/1984 Sackner et al. * 4,503,035 03/1985 Pestka et al. * 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,599,298 12/1985 Fahy * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,614,730 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,790,305 12/1988 Shaner * 4,780,54 10/1988 Newell et al. * 4,808,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,238 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,238 04/1989 Borkoni et al.	Initial		Patent No.	Date	Patentee	Class	Class	Date
* 4,446,862 05/1984 Baum et al. * 4,446,862 05/1984 Malem * 4,452,239 06/1984 Malem * 4,484,577 11/1984 Sackner et al. * 4,503,035 03/1985 Pestka et al. * 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,599,298 12/1985 Fahy * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,779,0305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al.		*	4,338,931	07/1982	Cavazza			
* 4,452,239 06/1984 Malem * 4,484,577 11/1984 Sackner et al. * 4,530,035 03/1985 Pestka et al. * 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,779,0305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,811,731 03/1989 Newell et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al.		*	4,423,079	12/1983	Kline			
* 4,484,577 11/1984 Sackner et al. * 4,503,035 03/1985 Pestka et al. * 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,559,0298 12/1985 Fahy * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,677,975 07/1987 Edgar et al. * 4,679,328 10/1987 Neer et al. * 4,698,328 10/1987 Neer et al. * 4,778,054 10/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,446,862	05/1984	Baum et al.			
* 4,503,035 03/1985 Pestka et al. * 4,503,035 03/1985 Kawamata et al. * 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,559,298 12/1985 Fahy * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,649,911 03/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,780,305 12/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,452,239	06/1984	Malem			
* 4,533,552 08/1985 Kawamata et al. * 4,534,343 08/1985 Nowacki et al. * 4,559,298 12/1985 Fahy * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,484,577	11/1984	Sackner et al.			
* 4,534,343 08/1985 Nowacki et al. * 4,534,343 08/1985 Nowacki et al. * 4,559,298 12/1985 Fahy * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,624,251 11/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,811,731 03/1989 Newell et al. * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,503,035	03/1985	Pestka et al.			
* 4,559,298 12/1985 Fahy * 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,533,552	08/1985	Kawamata et al.		-	
* 4,590,206 05/1986 Forrester et al. * 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,306,343 02/1989 Carpenter et al. * 4,806,343 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,820,534 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,534,343	08/1985	Nowacki et al.			
* 4,599,311 07/1986 Kawasaki * 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,823,784 04/1989 Borkoni et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,559,298	12/1985	Fahy			
* 4,614,730 09/1986 Hansen * 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,590,206	05/1986	Forrester et al.			
* 4,617,272 10/1986 Kirkwood et al. * 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,599,311	07/1986	Kawasaki		·	
* 4,624,251 11/1986 Miller * 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,811,731 03/1989 Newell et al. * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,614,730	09/1986	Hansen			
* 4,627,432 12/1986 Newell et al. * 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,823,784 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,617,272	10/1986	Kirkwood et al.			
* 4,649,911 03/1987 Knight et al. * 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,624,251	11/1986	Miller			
* 4,659,696 04/1987 Hirai et al. * 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,627,432	12/1986	Newell et al.			
* 4,677,975 07/1987 Edgar et al. * 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,649,911	03/1987	Knight et al.			
* 4,698,328 10/1987 Neer et al. * 4,729,754 04/1988 Shaner * 4,778,054 10/1988 Newell et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,659,696	04/1987	Hirai et al.			
* 4,729,754		*	4,677,975	07/1987	Edgar et al.			
* 4,729,734 04/1988 Shaher * 4,778,054 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,698,328	10/1987	Neer et al.			
* 4,778,034 10/1988 Newell et al. * 4,790,305 12/1988 Zoltan et al. * 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,729,754	04/1988	Shaner			
* 4,806,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,778,054	10/1988	Newell et al.			
* 4,800,343 02/1989 Carpenter et al. * 4,807,814 02/1989 Douche et al. * 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,790,305	12/1988	Zoltan et al.			
* 4,811,731 03/1989 Newell et al. * 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,806,343	02/1989	Carpenter et al.			
* 4,819,629 04/1989 Jonson * 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,807,814	02/1989	Douche et al.			
* 4,820,534 04/1989 Saleeb et al. * 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,811,731	03/1989	Newell et al.			
* 4,823,784 04/1989 Borkoni et al. * 4,824,938 04/1989 Koyama et al.		*	4,819,629	04/1989	Jonson		_	
* 4,824,938 04/1989 Koyama et al.		*	4,820,534	04/1989	Saleeb et al.			
4,024,936 04/1909 Royalila et al.		*	4,823,784	04/1989	Borkoni et al.			
* 4,830,858 05/1989 Payne et al.		*	4,824,938	04/1989	Koyama et al.			
		*	4,830,858	05/1989	Payne et al.			

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Examiner						Sub-	Filing
Initial		Patent No.	Date	Patentee	Class	Class	Date
	*	4,833,125	05/1989	Neer et al.			
	*	4,855,157	08/1989	Tashiro et al.			
	*	4,857,319	08/1989	Crowe et al.			
	*	4,876,241	10/1989	Feldman et al.			
	*	4,884,565	12/1989	Cocozza			
	*	4,889,114	12/1989	Kladders		-	
•	*	4,891,319	01/1990	Roser	Ĺ		
	*	4,895,719	01/1990	Radhakrishnan et al.			
	*	4,897,353	01/1990	Carpenter et al.			
	*	4,907,583	03/1990	Wetterlin et al.			
	*	4,919,962	04/1990	Arora et al.			
	*	4,926,852	05/1990	Zoltan et al.			
	*	4,927,763	05/1990	Sudoma et al.			
	*	4,931,361	06/1990	Baldeschwieler et al.			
	*	4,942,544	07/1990	McIntosh et al.			
	*	4,946,828	08/1990	Markussen			
	*	4,956,295	09/1990	Sudoma			
	*	4,968,607	11/1990	Dower et al.			
	*	4,984,158	01/1991	Hillsman			
	*	4,995,385	02/1991	Valentini et al.			
	*	5,011,678	04/1991	Wang et al.	1		
	*	5,017,372	05/1991	Hastings			
	*	5,026,566	06/1991	Foster			
	*	5,027,806	07/1991	Zoltan et al.			
	*	5,033,463	07/1991	Cocozza			
	*	5,035,237	07/1991	Newell et al.			
	*	5,042,975	08/1991	Chien et al.			
	*	5,048,514	09/1991	Ramella			
	*	5,049,388	09/1991	Kright et al.			
	*	5,081,228	01/1992	Dower et al.		_	

Examiner:	Date Considered:

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:
	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S.	Patton et al.
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner				-		Sub-	Filing
Initial		Patent No.	Date	Patentee	Class	Class	Date
	*	5,093,316	03/1992	Lezdey et al.			
	*	5,098,893	03/1992	Franks et al.			
	*	5,099,833	03/1992	Michaels			
	*	5,113,855	05/1992	Newhouse			
	*	5,124,162	06/1992	Boskovic et al.	_		
	*	5,139,016	08/1992	Waser			
	*	5,149,543	09/1992	Cohen et al.			
	*	5,149,653	09/1992	Roser			
	*	5,161,524	11/1992	Evans			
	*	5,180,812	01/1993	Dower et al.			
	*	5,186,164	02/1993	Raghuprasad			
	*	5,200,399	04/1993	Wettlaufer et al.			
	*	5,204,108	04/1993	Illum			
	*	5,206,200	04/1993	Bush et al.			
	*	5,230,884	07/1993	Evans et al.			
	*	5,253,468	10/1993	Raymond			
	*	5,254,330	10/1993	Ganderton			
	*	5,260,306	11/1993	Boardman et al.			
	*	5,290,765	03/1994	Wettlaufer et al.			
	*	5,295,479	03/1994	Lankinen			
	*	5,302,581	04/1994	Sarin et al.			1
	*	5,309,900	05/1994	Knoch et al.			1
	*	5,320,094	06/1994	Laube et al.			Ī
	*	5,320,714	06/1994	Brendel			
	*	5,331,953	07/1994	Anderson et al.			
	*	5,354,562	10/1994	Platz			
	*	5,354,934	10/1994	Pitt et al.			
	*	5,356,635	10/1994	Raman et al.			
	*	5,364,838	11/1994	Rubsamen	-		
	*	5,376,359	12/1994	Johnson			

Examiner:	Date Considered:

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:	
	0005.16	10/613,078	
Information Disclosure	Applicant:		
Statement By Applicant	John S. Patton et al.		
	Filing Date:	Group:	
(Use Several Sheets if Necessary)	07/01/2003	1616	

Examiner						Sub-	Filing
Initial		Patent No.	Date	Patentee	Class	Class	Date
	*	5.384,133	01/1995	Boyes et al.			ľ
	*	5,376,386	12/1994	Ganderton			
	*	5,419,315	05/1995	Rubsamen			
	*	5,447,151	09/1995	Bruna et al.			
	*	5,458,135	10/1995	Patton			
	*	5,482,927	01/1996	Maniar et al.			
	*	5,506,203	04/1996	Backstrom et al.			
	*	5,518,998	05/1996	Backstrom et al.			
	*	5,558,085	09/1996	Rubsamen et al.			
	*	5,619,984	04/1997	Hodson et al.			
	*	5,672,581	09/1997	Rubsamen et al.			
	*	5,755,221	05/1998	Bisgaard		-	
	*	5,997,848	12/1999	Patton et al.			
	*	6,012,454	01/2000	Hodson et al.			
	*	6,019,968	02/2000	Platz et al.			
	*	6,051,256	04/2000	Platz et al.			
	*	6,099,517	08/2000	Daugherty			
	*	6,402,733	06/2002	Daugherty			
	*	6,582,728	06/2003	Platz et al.			
	*	6,685,967	02/2004	Patton et al.			
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Examiner:	Date Considered:

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:
İ	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S.	Patton et al.
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Foreign Patent or Published Foreign Patent Application

Examiner		Document	Publication	Country or		Sub-	Trans	lation
Initial	No.	No.	Date	Patent Office	Class	class	Yes	No
	*	902 257	08/1985	BE				
	*	18 12 574	06/1970	DE				
	*	24 15 159	10/1975	DE				
	*	31 41 498	04/1983	DE				
	*	01 61 072	09/1984	DE				
	*	0 015 123	09/1980	EP				
	*	0 072 046	02/1983	EP	İ			
	*	0 111 216	06/1984	EP				
	*	0 122 036	10/1984	EP				
	*	0 140 489	05/1985	EP				
	*	0 193 372	09/1986	EP				_
	*	0 229 810	07/1987	EP				
	*	0 237 507	09/1987	EP				
	*	0 289 336	11/1988	EP				
	*	0 302 772	02/1989	EP				
	*	0 347 779	12/1989	EP				
	*	0 360 340	03/1990	EP			-	
	*	0 364 235	04/1990	EP				
	*	0 366 303	05/1990	EP				
	*	0 383 569	08/1990	EP				
	*	0 468 914	01/1992	EP				
	*	0 467 172	01/1992	EP				
	*	0 490 797	06/1992	EP				
	*	0 506 293	09/1992	EP				
	*	0 611 567	08/1994	EP				
	*	0 655 237	05/1995	EP				
	*	8403520	02/1983	ES				
	*	2257351	01/1974	FR				
	*	1 288 094	09/1972	GB				
	*	1 477 775	06/1977	GB				

1		
	Examiner:	Date Considered:

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:	
İ	0005.16	10/613,078	
Information Disclosure Statement By Applicant	Applicant: John S. Patton et al.		
	Filing Date:	Group:	
(Use Several Sheets if Necessary)	07/01/2003	1616	

Foreign Patent or Published Foreign Patent Application

Examiner		Document	Publication	Country or		Sub-	Trans	lation
Initial	No.	No.	Date	Patent Office	Class	class	Yes	No
	*	1 527 605	10/1978	GB				
	*	2 105 189	03/1983	GB				
	*	2 126 588	03/1984	GB				
	*	56138110	10/1981	JP				
	*	56138111	10/1981	JP				
	*	62267238	11/1987	JP				
	*	59095885	02/1984	JP				
	*	61293201	12/1986	JP				
	*	7712041	05/1979	NL				
	*	0628930	09/1978	RU				·
	*	1003926	03/1983	RU				
	*	0883174	11/1981	RU				
	*	84/00294	02/1984	WO				
	*	86/04095	07/1986	WO			ļ	-
	*	87/00196	01/1987	WO				
	*	87/05300	09/1987	wo				
	*	88/04556	06/1988	WO				
	*	88/09163	12/1988	WO				
	*	90/04962	05/1990	WO		-		
	*	90/05182	05/1990	WO				
	*	90/07351	07/1990	WO				
	*	90/09780	09/1990	WO				12
	*	90/15635	12/1990	WO		 ·		
	*	91/02545	03/1991	WO				
	*	91/02558	03/1991	WO	İ			
	*	91/06282	05/1991	WO				
	*	91/16038	10/1991	WO				
	*	91/16882	11/1991	WO				
	*	92/10229	06/1992	WO				
	*	93/00951	01/1993	WO				

Examiner:	Date Considered:	

Form PTO/SB/08A (Modified)	Atty Docket No.:	Application No.:	
	0005.16	10/613,078	
Information Disclosure	Applicant:		
Statement By Applicant	John S. Patton et al.		
	Filing Date:	Group:	
(Use Several Sheets if Necessary)	07/01/2003	1616	

Foreign Patent or Published Foreign Patent Application

Examiner		Document	Publication	Country or		Sub-	Trans	lation
Initial	No.	No.	Date	Patent Office	Class	class	Yes	No
	*	93/02712	02/1993	wo				
	*	93/09832	05/1993	wo				
	*	94/08552	04/1994	WO				
	*	95/00127	01/1995	WO				
	*	95/23613	09/1995	WO				
	*	96/09814	04/1996	WO				
	*	97/03649	02/1997	WO				
	*	94/00155	07/1995	ZA				_
			-					***
							-	
						-		

Examiner:	Date Considered:	

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	pplicant John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner			
Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication	
	*	ANDREWS, "Gelatin Capsules Revamped for New Generation of Pills," New York Times, Saturday, September 16, 1992, 19(N), 35(L), col. 5, 9 col. in.	
	*	ANNEAR, "Observations on Drying Bacteria from the Frozen and from the Liquid State," Austral. J. Exp. Biol. (1958), 36:211-221.	
	*	BJÖRK ET AL., "Degradable Starch Microspheres as a Nasal Delivery System for Insulin" International J. of Pharmaceutics (1988), 47:233-238.	
	*	BOHNET, "Calculation and Design of Gas/Solid-Injectors," Powder Tech. (1984), pp. 302-313.	
	*	BONE ET AL., "Dielectric Studies of Protein Hydration and Hydration-Induced Flexibility," J. Mol. Biol. (1985), 181:323-326.	
	*	BRUNI ET AL., "Glass Transitions in Soybean Seed, Relevance to Anhydrous Biology," Plant Physiol. (1991), <u>96</u> :660-663.	
	*	BUDRIK ET AL., "Ejector Feeders for Pneumatic Transport Systems," Chemical & Petroleum Engineering, SepOct. 1978, 14(9-10):9-10.	
	*	BURKE, "The Glassy State and Survival of Anhydrous Biological Systems," Membranes, Metabolism and Dry Organisms, Appendix D, 1986, A. Carl Leopold Editor, pp. 358-363.	
	*	BYRON ET AL., "Drug Delivery Via the Respiratory Tract," J. of Aerosol Medicine (1994), 7(1):49-75	
	*	CAFFREY ET AL., "Lipid-Sugar Interactions, Relevance to Anhydrous Biology," Plant Physiol. (1988), <u>86</u> :754-758.	
	*	CARPENTER ET AL., "Stabilization of Phosphofructokinase During Air- Drying with Sugars and Sugar/Transition Metal Mixtures," Cryobiology (1987), 24:455-464.	
	*	CARPENTER ET AL., "Stabilization of Phosphofructokinase with Sugars During Freeze-Drying: Characterization of Enhanced Protection in the Presence of Divalent Cations," Biochimica et Bipophysica Acta (1987), 923:109-115.	
	*	CARPENTER ET AL., "Modes of Stabilization of a Protein by Organic Solutes During Desiccation," Cryobiology (1988), <u>25</u> :459-470.	
	*	CHIEN ET AL., "Intranasal Drug Delivery for Systemic Medications," CRC Critical Reviews in Therapeutic Drug Carrier Systems (1987), 4(2):67-92.	
	*	CHOPIN ET AL., "Destruction de Microbacterium Lacticum, Escherichia coli et Staphylococcus Aureus au cours du schage du lait par atomisation," Can. Microbiol. (1977), 23:716-720. No translation.	
Examiner:		Date Considered:	

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
i	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S.	Patton et al.
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner			
Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication	
	*	COLTHROPE ET AL., "The Pharmacokinetics of Pulmonary-Derived Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," Pharm. Res. (1992), 9(6):764-768.	
	*	CROWE ET AL., "Stabilization of Dry Phospholipid Bilayers and Proteins by Sugars," Biochem. J. (1987), 242:1-10.	
	*	CROWE ET AL., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules," Cryobiology (1990), <u>27</u> :219-231.	
	*	DUCHATEAU, "Bile Salts and Intranasal Drug Absorption," International J. of Pharmaceutics (1986), 31:193-199.	
	*	DOLOVICH, "Lung Dose, Distribution, and Clinical Response to Therapeutic Aerosols," Aerosol Sci. and Tech. (1993), 18:230-240.	
	*	ELLIOT ET AL., "Parental Absorption of Insulin for the Lung in Diabetic Children," Aust. Paediatr. J. (1987), 23:293-297.	
	*	FAHY, "The Relevance of Cryoprotectant 'Toxicity' to Cryobiology," Cryobiology (1986), 23:1-13.	
	*	FINNEY ET AL., "Protein Hydration and Enzyme Activity: The Role of Hydration Induced Conformation and Dynamic Changes in the Activity of Lysozyme," Comments Mol. Cell. Biophys. (1984), 2(3-4):129-151.	
	*	FLINK, Chapter 17 entitled "Structure and Structure Transitions in Dried Carbohydrate Materials," Physical Properties of Foods, 1983, M. Peleg and E. B. Bagley (Editions), pp. 473-521.	
	*	FOX ET AL., "Performance of a Venturi Eductor as a Feeder in a Pneumatic Conveying System," Powder & Bulk Engineering, March 1988, pp. 33-36.	
	*	FRIEDMANN, "Progress Toward Human Gene Therapy," Science June 16, 1989, 244:1275-1281.	
	*	GÄNSSLEN, "Uber Inhalation Von Insulin" Klin. Wochenschr. January 1925, 4:71, (with translation).	
	*	GENDLER ET AL., "Permethyk Analogue of the Pyrrolic Antibiotic Disctamycin A," J. Med. Chem. (1981), 24(1):33-38.	
	*	GOETZ, Editor, Chapter Climate and Weather entitled "Atmospheric Humidity and Precipitation," The New Encyclopedia Britannica (1985), 16:476-479.	
	*	GOVINDA, "Aerosol Insulin Inhalation Enquiry,' Indian J. Physiol. Pharmacol. (1959), 3:161-167.	
Examiner:		Date Considered:	

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
j	0005.16	10/613,078
Information Disclosure Statement By Applicant	Applicant: John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	GREEN ET AL., "Phase Relations and Vitrification in Saccharide-Water Solutions and The Trehalose Anomaly," J. Phys. Chem. (1989), 93:2880-2882.
	*	HABENER, "Parathyroid Hormone: Secretion and Metabolism In Vivo," Proc. Nat. Acad. Sci., USA, Dec. 1971, <u>68</u> (12):2986-2991.
	*	HASTINGS ET AL., Clearance of Different-Sized Proteins from the Alveolar Space in Humans and Rabbits" J. Appl. Physiol. (1992), 73:1310-1316.
	*	HEINEMANN ET AL., "Time-Action Profile of Inhaled Insulin," Diabetic Medicine (1997), 14:63-72.
	*	HERRINGTON, "Some Physico-Chemical Properties of Lactose: The Spontaneous Crystallization of Super-Saturated Solutions of Lactose," J. Dairy Science (1934), 17:501-518.
	*	HESCH, "Pulsatile Secretion of Parathyroid Hormone and Its Action on a Type I and Type II PTH Receptor: A Hypothesis for Understanding Osteoporosis," Calcified Tissue Int. (1988), 42:341-344.
	*	HUBBARD ET AL., "Strategies for Aerosol Therapy of α ₁ -Antitrypsin Deficiency by the Aerosol Route," Lung, 1990, <u>168</u> , Supplement 1990, Proceedings of the 8 th Congress of SEP, Edited by H. Matthys, pp. 565-578.
	*	IIJIMA ET AL., "A Method for Preservation of Bacteria and Bacteriophages by Drying in Vacuo," Cryobiology (1973), 10:379-385.
	*	JOSIC, "Optimization of Process Conditions for the Production of Active Dry yeast," Lebensm-Wiss. U. Technol. (1982), <u>15</u> (1):5-14.
	*	KAREL, "Water Relation of Foods," R. B. Duckworth, Ed. (1975), Academic Press, NY, pp. 648-649.
	*	KAUZMANN, "The Nature of the Glassy State and The Behavior of Liquids at Low Temperatures," Department of Chemistry, Princeton University, Princetown, New Jersey, Received March 1, 1948, pp. 219-227.
	*	KIM ET AL., "Survival of Lactic Acid Bacteria During Spray Drying of Plain Yogurt," J. of food Sci. (1990), 55(4):1008-1010, 1048.
	*	KÖHLER, Diabetes JADA, February 1984 (Abstract).
Evanina	*	KÖHLER, "Islet Alteration in Vitro by Human Lymphocytes and Serum Before and After Manifestation of Type 1 (Insulin-Dependent) Diabetes Mellitus," May 1986, Diabetes, 35, Supplement 1, Program 46 th Annual Meeting, Minutes of the 21 st General Assembly of the European Association for the Study of Diabetes, p. 559A, No. 270 in the Abstract Part.

<u></u>			
Examiner:	Date Considered:	Date Considered:	

Form PTO/SB/08B (Modified) Atty Docket No.: Applic		Application No.:
į	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	t John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
Initial	*	KÖHLER ET AL., "Nicht Radioaktives Verfahren Zur Messung Der Lungenpermeabilität: Inhalation Von Insulin," Atemu. Lugenkrkh. Jahrgang (1987), 13(6):230-232. For English Abstract see Schlüter Reference.
	*	KÖHLER, "Aerosols for Systemic Treatment," Lung (1990), pp. 667-684.
	*	KÖHLER, Chapter 12 entitled "Systemic Therapy With Aerosols," Aerosols in Medicine, Principles, Diagnosis and Therapy, 2 nd ed. (1993), published by Elsevier, pp. 303-319.
	*	LABUZA ET AL., "Engineering Factors in Single-Cell Protein Production' Biotechnology and Bioengineering (1970), 12:135-140.
	*	LAUBE ET AL., "Preliminary Study of the Efficacy of Insulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" JAMA (1993), 269(16):2106-2109.
	*	LEE ET AL., "Development of an Aerosol Dosage Form Containing Insulin" J. of Pharmaceutical Sci. (1976), 65(4):567-572.
	*	LEVINE ET AL., "A Polymer Physico-Chemical Approach to the Study of Commercial Starch Hydrolysis Products (SHPs)," Carbohydrate Polymers (1986), 6:213-244.
	*	LEVINE ET AL., "Principles of 'Cryostabilization' Technology From Structure/Property Relationships of Carbohydrate/Water Systems," Cryo-letters (1988), 9:21-63.
	*	LIU E AL., "Pulmonary Delivery of Free and Liposomal Insulin" Pharmaceutical Research (1993), 10(2):228-232.
	*	MALIK, "A Simplified Liquid-Drying Method for the Preservation of Microorganisms Sensitive to Freezing and Freeze-Drying," J. of Microbiological Methods (1990), 12:125-132.
	*	METWALLY ET AL., "Spray Drying of Lactic Acid Culture, I. The Effect of Spray Drying Conditions on the Survival of Microorganisms," Egyptian J. Dairy Sci. (1989), <u>17</u> :35-43.
	*	METWALLY ET AL., "Spray Drying of Lactic Acid Cultures, II. The Effect of Culture Conditions and Storage on Microorganisms,' Egyptian J. Dairy Sci. (1989), 17:273-275, 278.

Examiner:	Date Considered:

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	MUMENTHALER ET AL., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," Pharmaceutical Research (1994), 11(1):12-20, Plenum Publishing Corporation.
	*	NAGAI ET AL., "Powder Dosage Form of Insulin for Nasal Administration" J. of Controlled Release (1984), 1:15-22.
	*	NAGANO ET AL., "New Method of Insulin Therapy: Transpulmonary Absorption of Insulin" Jikeikal Med. (1985), 32(3):503-506.
	*	NEER ET AL., "The Use of Parathyroid Hormone Plus 1, 25- Dihydroxyvitamin D to Increase Trabecular Bone in Osteoporotic Men and Postmenopausal Women," Osteoporosis (1987), <u>53</u> :829-835.
	*	NIEMINEN ET AL., "Aerosol Deposition in Automatic Dosimeter Nebulization, Eur. J. Respir. Dis. (1987), 71:145-152.
	*	PATTON ET AL., "(D) Routes of Delivery: Case Studies(2) Pulmonary Delivery of Peptides and Proteins for Systemic Action," Advanced Drug Delivery Reviews (1992), 8:179-196.
	*	PERI ET AL., "Thermodynamics of Water Sorption on Sacc. Cerevisiae and Cell Viability During Spray-Drying," Lebensm - Wiss. U. Technol. (1974), 7(2)76-81.
	*	PIKAL ET AL., "Moisture Transfer From Stopper to Product and Resulting Stability Implications," Developments in Biological Standardization (1991), 74:165-179, International Symposium on Biological Product Freeze-Drying and Formulation.
	*	PIKAL, "Polymorphisms in Pharmaceutical Solids," AAPS, November 15-19, 1992, Annual Meeting and Expositions, San Antonio, TX, 2 pages.
	*	PITTMAN ET AL., "Pneumatic Conveying of Bulk Solids Using a Vacuum Aerated Feed Nozzle," Solid Handling Conference Paper C4, June 10-12, 1986, Thames Polytechnic London, United Kingdom, pp. C41-C51.
	*	POOLE ET AL., "Hydration-Induced Conformational and Flexibility Changes in Lysozyme at Low Water Contents," Int. J. Biol. Macromol., October 1983, 5:308-310.
	*	POOLE ET AL., "Sequential Hydration of a Dry Globular Protein," Biopolymers (1983), 22:255-260.

Examiner:	Date Considered:

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S. Patton et al.	
·	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner		
Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	PRAJAPATI ET AL., "Survival of Lactobacillus Acidophilus in Blended - Spray Dried Acidophilus Preparations," Australian J. of Dairy Technology, March/June 1987, pp. 17-21.
	*	RAO, "Aerosol Insulin Inhalation Enquiry," Indian J. Physiol. Pharmacol. (1959), 3:161-167.
	*	ROOS ET AL., "Effects of Glass Transitions on Dynamic Phenomena, Figure 10.8," The Glassy State in Foods, published by J. M. Blanchard and P. J. Lillford (Nillington University Press) 1993, one page.
	*	ROSENFELD ET AL., "Adenovirus-Mediated Transfer of a Recombinant α-1-Antitryspin Gene to the Lung Epithelium in Vivo," Science, April 19, 1991, 252:431-434.
	*	ROSER, "Trehalose Drying: A Novel Replacement for Freeze-Drying," Biopharm., September 1991, 4(8):47-53.
	*	RYDEN ET AL., "Effect of Polymers and Microspheres on the Nasal Absorption of Insulin in Rats," International J. of Pharmaceutics (1992), 83:1-10.
	*	SAKR, "A New Approach for Insulin Delivery via the Pulmonary Route: Design and Pharmcokinetics in Non-Diabetic Rabbits" International J. of Pharmaceuticals (1992), 86:1-7.
	*	SCHLUTE ET AL., Abstract Diabetes (1984), <u>13(6)</u> :230-232.
	*	SCHNEIDER ET AL., "Thermostability of Enzyme in the Three-Dimensional Network of Polisaccharide Chains," Bulletin de 1 'Academie Polonaise des Sciences (1968), Cl. II, Vol. XVI, No. 4, 1968, Serie des Sciences Biologiques, pp. 203-204.
	*	SKRABANJA ET AL., "Lyophilization of Biotechnology Products," PDA J. of Pharmaceutical Sci. & Tech., November-December 1994, 48(6):311-317.
	*	SLADE ET AL., "Structural Stability of Intermediate Moisture Food - A New Understanding?" Food Structure, Its Creation and Evaluation (1988), pp. 115-147.
	*	STRIBLING ET AL., "The Mouse as a Model for Cationic Liposome-Based, Aerosolized Gene Delivery," J. of Biopharmaceutical Sci. (1992), 3 (1/2), pp. 255-263.

Date Considered:
Date Considered.

Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	TERTYSHNY ET AL., "Effect of Orthophosphoric Acid on Survivability of Proionibacterium Shermanii After Spray Drying and in the Process of Storage," Microbiology J. (1988), 50(3):49-52, English Summary on p. 52.
	*	TOWNSEND ET AL., "Use of Lyoprotectants in the Freeze-Drying of a Model Protein, Ribonuclease A," J. of Parenteral Sci. & Tech., November-December 1988, 42(6):190-199.
	*	TSOUROUFLIS ET AL., "Loss of Structure in Freeze-Dried Carbohydrates Solutions: Effect of Temperature, Moisture Content and Composition," J. Sci. Fd Agric. (1976), <u>27</u> :509-519.
	*	UEDAIRA ET AL., "The Effect of Sugars on the Thermal Denaturation of Lysozyme," Bulletin of the Chemical Society of Japan, September 1980, 53:2451-2455.
	*	UNDERWOOD ET AL., "A Novel Technique for the Administration of Bronchodilator Drugs Formulated as Dry Powders to the Anaesthetized Guinea Pig," J. of Pharmacological Methods (1991), 26:203-210.
	*	VAN DE BEEK ET AL., "Preservation of the Enzymatic Activity of Rennin During Spray Drying and During Storage, and the Effect of Sugar and Certain other Activities," Neth. Milk Dairy J. (1969), 23:46-54.
	*	WETTLAUFER ET AL., "Relevance of Amadori and Maillard Product to Seed Deterioration," Plant Physiol, April 1991, 97:165-169.
	*	WHITE ET AL., "The Glassy State in Certain Sugar-Containing Food Products," J. Food Technol. (1966), 1:73-92.
	*	WIGLEY ET AL., "Insulin Across Respiratory Mucosae by Aerosol Delivery," Diabetes (1971), 20(8):552-556.
	*	WILLIAMS ET AL., "Vial Breakage by Frozen Mannitol Solutions: Correlation with Terminal Characteristics and Effect of Stereoisomerism, Additives, and Vial Configuration, "J. of Parenteral Sci. & Tech., March-April 1991, 45(2):94-100.
	*	WILLIAMS ET AL., "The Glassy State in Corn Embryos," Plant Physiol. (1989), 89:977-981.
	*	WITHAM, "Dry Dispersion with Sonic Velocity Nozzles," Workshop on Dissemination Techniques for Smoke and Obscurants Chemical Systems Laboratory, Aberdeen Proving Group, MD, March 14-16, 1983, pp. 1-26.

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Form PTO/SB/08B (Modified)	Atty Docket No.:	Application No.:
1	0005.16	10/613,078
Information Disclosure	Applicant:	
Statement By Applicant	John S. Patton et al.	
	Filing Date:	Group:
(Use Several Sheets if Necessary)	07/01/2003	1616

Examiner		
Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	YOSHIDA ET AL., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form," J. of Pharmaceutical Sci., May 1979, 68(5):670-671.
	*	ZHOLOB ET AL., "Effect of Injector Unit Design on the Particle Size of Atomized Powder," 0038-5735/79/1806, 1979 Plenum Publishing Corporation, pp. 362-354, Dnepropetrovsk State University, Translated from Poroshkovaya Metallurgiya, June 1979, No. 6(198), pp. 13-16, original article submitted August 1, 1978.
	*	Abstracts, 18 th Annual Meeting, Cryobiology, Vol. 18, No. 6, December 1981, see Numbers 20 page 617 & 24 page 618. Author Gregory Fahy.
	*	Abstract - Japanese Patents Gazette - Week 8604 - April 12, 1985, Section Chemical JP 60244288-A, Applicant: Okura Seiyaku KK, one pages, and translation in English.
	*	Abstract – Japanese Patents Gazette – Week 8746 – July 10, 1987, Section Chemical JP 62228272-A, Applicant: Amano Pharm. KK, one page.
	*	Abstract - Japanese Patent Gazette - Week 8750 - Section Chemical JP 62255434-A Fuji Seiyu KK - November 7, 1987 - Inventors: Tagawa Kunio and Kurosawa Wahei - Applicant: Fuji Oil Co. Ltd.
	*	"Clean-Up with Pulsed Jets," Manufacturing Chemist, April 1992, pp. 29, 31.
	*	Drytec, Compact Laboratory Dryer, Undated Brochure, one page.
	*	Lab-Plant Ltd., SD-04 Laboratory Scale Spray Drier, Undated Brochure, 4 pages.
	*	Pharmacia LKB Biotechnology Brochure entitled "A Cure for the Common Cold- Ready to go DNA Labeling Kit Pre-Mixed Reactions that Store at Room Temperature," Undated, 9 pages.
	*	"Production of Trehalose Dried Eggs," D5, Tg Measurements, Undated, 10 pages.
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